RECORD AND BRIEFS

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IN THE

Supreme Court of the United States

LIFE TECHNOLOGIES CORPORATION; INVITROGEN IP HOLDINGS, INC.; APPLIED BIOSYSTEMS, LLC,

Petitioners,

v.

PROMEGA CORPORATION,

Respondent.

On Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

BRIEF OF *AMICUS CURIAE* WISCONSIN ALUMNI RESEARCH FOUNDATION IN SUPPORT OF RESPONDENT

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I. STATEMENT OF INTEREST[1]

Amicus Curiae Wisconsin Alumni Research Foundation ("WARF") was founded in 1925 as a nonprofit entity to promote, encourage, and aid scientific investigation and research at the University of Wisconsin-Madison ("UW-Madison"). One of WARF's earliest accomplishments was to patent a Vitamin D discovery that eventually eliminated the childhood disease of rickets worldwide. Other significant advancements from UW-Madison and WARF include lifesaving organ transplant technology, faster computer processors, and Coumadin, the revolutionary treatment for cardiovascular disease.

WARF's portfolio includes more than 1,600 patented technologies covering a wide range of categories including pharmaceuticals, agriculture, food products, medical devices, pluripotent stem cells, clean technology, information technology and semiconductors. WARF has returned more than $ 2.3 billion in licensing revenue, adjusted for inflation, to UW-Madison and the Morgridge Institute of Research to fund research programs and initiatives.

In recognition of WARF's contributions to science and technology, WARF was awarded the National

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[1] The parties have consented to the filing of this brief in global consents to the filing of amicus briefs in support of any party. In accordance with Rule 37.6, no counsel for a party authored this brief in whole or in part, and no person or entity, other than WARF or its counsel, has made any monetary contributions to the preparation or submission of this brief.

Medal of Technology in 2005—the nation's highest honor for technology innovation.

II. INTRODUCTION AND SUMMARY OF THE ARGUMENT

The Court should preserve the strength of the U.S. patent system. University research is critical to innovation in this country. And strong U.S. patents are critical to incentivizing investments in research. Any change in patent law that reduces the perceived ability to protect investments in intellectual property, including any change in the Federal Circuit's interpretation of 35 U.S.C. § 271(f)(1), will negatively affect university research and the technology transfer sector.

At the time that Congress enacted § 271(f), Congress was attempting to stimulate innovation and strengthen patent law. This is apparent from the 1980 enactment of the Bayh-Dole Act, the highly successful legislation that gave rise to the technology transfer sector in American universities. Only a short time later, in 1984, Congress amended the Bayh-Dole Act and enacted § 271(f).

The cause of action in § 271(f) is already narrow. The perceived negative effects of the Federal Circuit's ruling posited by others are unlikely to occur because there are adequate safeguards in place to ensure that the provision does not exceed its intended scope.

The Court should affirm the Federal Circuit decision; reversal is not appropriate or necessary at this time, and the Federal Circuit and the jury were both correct that *Taq* polymerase is a qualitatively substantial component in the invention at issue.

III. ARGUMENT

A. Strong U.S. patents incentivize innovation.

A correlation exists between robust intellectual property protection and positive economic benefits, such as increased investment in research and development, high-value job growth, and increased innovative output. *See* Global Intellectual Property Center, U.S. Chamber of Commerce, *Unlimited Potential* 9-10 (3d ed. 2015). University and other federally funded research play an important role in innovation in this country, often providing the groundwork for start-up businesses and significant technological advances. Successful commercialization and application of the work resulting from this research is bolstered by protecting the intellectual property involved. Strong patent law helps American businesses prosper.

1. The 1980 Bayh-Dole Act granted patent ownership and license rights to universities to encourage innovation in this country.

University research plays a major role in the advancement of technology in the United States ("U.S."). Universities are the birthplace of new knowledge, discoveries, and technical know-how. Beyond basic research, new products, equipment, and instrumentation are also designed and tested in academic settings. Human capital embodied in students trained by American universities also directly benefits the business sector when those individuals become employees and business owners.

In 1980, Congress itself confirmed the importance of university research when it enacted the federal

Bayh-Dole Act. *See* 35 U.S.C. § 200-212; 37 C.F.R. Part 401. This landmark legislation gave universities the right to own and license patents resulting from federally funded research. The Act thus spurred significant transfer of technology and scientific knowledge from universities to businesses.

The reason that Congress enacted the Bayh-Dole Act was not to enrich universities, but to attempt to stimulate the pace of innovation and the American economy, which had slowed over the 1960s and 70s. Ashley J. Stevens, *The Enactment of Bayh-Dole*, 29 J. Tech. Transfer 93 (2004).

The Bayh-Dole Act has been a resounding success. Prior to the Bayh-Dole Act, when the federal government owned inventions resulting from federally funded research, fewer than 5% of the 28,000 federally owned patents were licensed to industry. Valerie Landrio McDevitt et al., *More than Money: The Exponential Impact of Academic Technology Transfer*, 16 Tech. Innov. 75 (2014). According to the 2014 AUTM Licensing Survey, conducted by the Association of University Technology Managers ("AUTM"), technology transfer activities from institutions including universities, hospitals and research institutes generated $28 billion in net product sales, 914 new start-up companies, and 965 new commercial products in that year. Ass'n of Univ. Tech. Managers (AUTM), *U.S. Licensing Activity Survey: FY 2014* 8, 10 (2014). Respondents to the AUTM survey also reported 6,363 new U.S. patents issued and 5,435 new licenses executed in 2014. *Id.* at 8. The survey concludes that "[c]ompanies spun out of research universities have a far greater success rate than

other companies, creating good jobs and spurring economic activity." *Id.* at 10. Indeed, 4,688 of companies born of technology transfer activities were still in business at the end of 2014. *Id.*

WARF is a leader in technology transfer and itself manages more than 700 pending and 1,850 issued U.S. patents on UW-Madison technologies, as well as over 2,000 foreign equivalents. WARF offers more than 2,000 technologies for licensing, and maintains more than 560 active commercial license agreements. WARF's most important patents include the blood anticoagulant Warfarin, a coating process making pills easier to swallow, treatments for osteoporosis and cancer, magnetic resonance techniques, and a discovery known as the "Wisconsin Solution" that prolongs the use of transplant organs. WARF's investment in research and technology has led to the creation of over 80 start-up companies.

The many benefits of university research are significant and quantifiable. It has been estimated that, assuming a 2% royalty and no product substitution effects, over a 15-year period from 1996-2010, university licensing agreements based on product sales contributed at least $70.5 billion and as much as $277.6 billion (2005 dollars) to the U.S. gross domestic product. David Roessner et al., *The Economic Impact of Licensed Commercialized Inventions Originating in University Research,* 42 Res. Pol'y 23, 23 (2013). Assuming moderately conservative royalties of 5%, such agreements would have contributed more than $122.2 billion to the gross domestic product. *Id.*

It follows that patents are critical for securing investments in university research and for developing and licensing university inventions. Private companies investing in and sponsoring research at universities want to protect the results of those research and development activities. Similarly, licensees of federally funded research rely on the patent system for stability in their rights. Strong U.S. patents are essential to the efforts of universities and institutions to transfer technology and launch start-up companies. Indeed, the success of the Bayh-Dole Act depends on a strong patent system. Any change in law that reduces the perceived ability of a patent owner or licensee to protect the results of research and development sponsored in universities will erode the willingness of private companies to seek a patent license or to sponsor research at a university.

2. In 1984, Congress enacted 35 U.S.C. § 271(f) to further strong patent rights.

The timing of the enactment of 35 U.S.C. § 271(f) is significant. In the 1980s, Congress intended to strengthen patent rights. In 1984, the year in which Congress enacted § 271(f)(1), (see Patent Law Amendment Act of 1984, Pub. L. No. 98-622, § 101, 98 Stat. 3383), Congress also amended the Bayh-Dole Act. During this time when Congress was strengthening patent rights, it could not have intended § 271(f) to be a trivial provision.

The specific reason that Congress enacted § 271(f) was to "prevent copiers from avoiding U.S. patents by supplying components of a patented product in this country so that the assembly of the

components may be completed abroad." 130 Cong. Rec. 28,069 (1984) (statement of Rep. Kastenmeier). The provision was, in part, a response to this Court's decision in *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518 (1972). *Id.*

The legislative history makes clear that the 1984 Congress sought strong patent law. The specific goal of the subcommittee sponsoring new § 271(f) was to "secure for the owners of intellectual property, including patent holders, a workable, efficient, and vigorous set of laws to protect their creations." 130 Cong. Rec. 28,069. Strong patent law is the way to implement that goal:

> It is only through implementation of the constitutional mandate of encouraging the sciences and the useful arts that we will be able to spur the inventive spirit that has made our country a world leader. Indeed, our ability to foster innovation is a central element to our national security, for without technological and scientific developments, we could not maintain our current standard of living or hope for the diminution of unemployment caused by foreign competition.

Id.

While the 1984 bill resulting in § 271(f) was "likely to be seen by most observers as mundane or technical in nature," those types of amendments are still important. *Id.* For "without enactment of these housekeeping-oriented measures, the patent system would not be responsive to the challenges of a

changing world and the public would not benefit from the release of creative genius." *Id.*

The petitioners (hereinafter "LifeTech"), as well as other amici curiae, argue that § 271(f) cannot cover the supply of a single component because Congress was only trying to address the loophole at issue in *Deepsouth Packing Co.* However, Congress's intent was clear, to allow "the patent system [to] be responsive to the challenges of a *changing* world." *Id.* (emphasis added). Therefore, Congress was not only attempting to close the loophole directly at issue in *Deepsouth Packing Co.*, but also to address other similar loopholes that may be raised in the future. Permitting liability where a party only supplies a single component furthers that goal.

In 1984, Congress also made amendments to the Bayh-Dole Act. *See* Pub. L. No. 98-620, § 501, 98 Stat. 3335, 3364-68 (1984). While these amendments were relatively minor, they did, among other things, eliminate prior restrictions on the terms of exclusive patent licenses. *Id.*

Based on these Congressional Acts, it is clear that, in the 1980s, Congress intended to promote strong patent law, including when it enacted § 271(f). The legislative history of § 271(f)(1) is entirely consistent with the textual statutory language and the Federal Circuit's decision. The 35 years since the passage of the Bayh-Dole Act have demonstrated that the goals addressed by these 1980s actions are still sound. And, the statistics discussed above demonstrate that the legislation has worked to encourage the transfer of technology from

universities to the business sector. There is, therefore, no need to reverse.

3. Patent law would be weakened, and innovation would be negatively affected, if § 271(f)(1) is construed narrowly.

Strong patent laws promote innovation, which facilitates economic growth. It is a virtuous circle with positive results. Strong patents incentivize companies to take licenses from patent owners, instead of taking the risks of infringement. Licenses result in royalty revenue to patent owners. Greater potential royalty revenue incentivizes inventors to invent and publicly disclose their inventions through the patent process.

When universities own patents, the revenue generated from licenses is directly reinvested in more research, improved facilities, and attracting talent to American universities. This leads to additional technological advancement and more technology available for licensing to the business sector.

Even specific statutory sub-parts, such as § 271(f)(1), are important to a regime of strong patent laws. Patent law would be weakened if § 271(f)(1) is construed to necessarily exclude parties that supply a single component from the U.S. and actively induce the combination of the component outside of the U.S. in a manner that would infringe if done within the country. For example, parties who supply those components would no longer take a license.

The perception of a weakened patent system may also encourage infringers. This would lead to less

licensing and less revenue for scientific investigation and research. An overly narrow interpretation of § 271(f)(1) would be inconsistent with the clear legislative intent of the 1984 Congress that enacted the provision.

B. The Federal Circuit's ruling should stand because the safeguards against overreach already in place for § 271(f)(1) are sufficient.

The Court should affirm the Federal Circuit's interpretation of § 271(f)(1) because there are already safeguards in place that prevent § 271(f)(1) from having an overbroad scope.

1. The facts of this case do not illuminate the safeguards.

Liability under § 271(f)(1) is relatively uncommon. And the provision already has meaningful safeguards against the provision having too broad a scope. But as explained below, the case at hand has unique facts that cause the discussion of these safeguards to fade to the background.

Promega Corporation is the exclusive licensee of the Tautz patent at issue, U.S. Patent No. RE 37,984. Pet. App. 5a. Claim 42 of the Tautz patent is the only one at issue now, and it covers a kit for analyzing DNA samples, where the kit comprises five components: a primer mix, a polymerizing enzyme, nucleotides, a buffer solution, and control DNA. *Id.* at 7a-8a. The polymerizing enzyme that LifeTech used was *Taq* polymerase. *Id.*

Promega asserted the Tautz patent against LifeTech. *Id.* at 9a. LifeTech manufactured the *Taq* polymerase required by claim 42 in the U.S., and

then shipped the component to its facility in the United Kingdom ("UK"). *Id.* at 8a. The UK facility then assembled the domestic component with four other components to make the kit which would infringe the Tautz patent if the kit were assembled in the U.S. *Id.* at 22a.

One unique aspect of this case relates to the inducement aspect of § 271(f)(1). The district court held that Promega waived its argument that the LifeTech entity shipping the component from the U.S. was a separate entity from the LifeTech facility in the UK that assembled the patented product. Opp'n Br. 15 n.5. This created a situation where LifeTech was deemed to be inducing itself under § 271(f)(1). Pet. App. 24a. This is unusual because the vast majority of businesses with international scope have different operating entities in different countries or regions. But in this case, "whether LifeTech exhibited the necessary knowledge and intent to combine the *Taq* polymerase with the remaining components of its genetic testing kit 'in a manner that would infringe' the Tautz patent if that combination occurred within the U.S. ***is not contested and presumed.***" *Id.* at 34a. (emphasis added). In most cases, there would be separate entities involved, and inducement would not be uncontested or presumed.

LifeTech, as well as other amici curiae, argue that under the Federal Circuit's decision, innocent domestic manufacturers shipping a component abroad are at a heightened risk for infringement. Pet. Br. 5, 38. This is not so; nor is it an accurate extrapolation of the Federal Circuit's holding. LifeTech was not an innocent domestic

manufacturer. LifeTech intended to and succeeded in inducing itself to combine the supplied component with other components in a manner that would infringe a patent if combined in the U.S.

Section 271(f)(1) is not intended to—and did not in this case—subject an innocent domestic component supplier to liability. To protect innocent domestic manufacturers shipping a component abroad, § 271(f)(1) contains an adequate safeguard because no liability attaches unless the requisite intent is found.

An additional safeguard on the scope of § 271(f)(1) is that the component or component supplied must constitute "a substantial portion of the components of the patented invention." This is a highly fact-specific inquiry; in this case, it was essentially admitted because "LifeTech's own witness testified that the *Taq* polymerase is one of the 'main' and 'major' components of the accused kits." Pet. App. 34a. The Federal Circuit even emphasized the fact-specific nature of its conclusion explaining that it was "based on the facts of this particular case." *Id.* at 28a.

2. Inducement is a crucial safeguard on the scope of infringement under § 271(f)(1).

The cause of action under § 271(f)(1) is already narrow. Unlike § 271(a) concerning traditional direct infringement, § 271(f)(1) is not a strict liability tort. Section 271(f)(1) requires active inducement:

> Whoever without authority supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a patented

> invention, where such components are uncombined in whole or in part, in such manner as to *actively induce* the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

35 U.S.C. § 271(f)(1) (emphasis added).

Under § 271(f)(1), "[a] finding of inducement requires both an underlying instance of direct infringement and a requisite showing of intent." *Liquid Dynamics Corp. v. Vaughan Co.*, 449 F.3d 1209, 1222 (Fed. Cir. 2006) (citation omitted).

Like § 271(f)(1), § 271(b) requires inducement. Section 271(f)(1) differs from 271(b) in what conduct must be induced. Section 271(f)(1) requires that the conduct being induced is "the combination of such components," while § 271(b) requires that the conduct being induced is "infringement of a patent." 35 U.S.C. §§ 271(f)(1), 271(b).

In the context of § 271(b), inducement has been described as that which "'cause[s], urge[s], encourage[s], or aid[s]' the infringing conduct." *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301, 1308 (Fed. Cir. 2012), *rev'd on other grounds*, 572 U.S. __, 134 S. Ct. 2111 (2014), quoting *Arris Grp., Inc. v. British Telecomms. PLC*, 639 F.3d 1368, 1379 n.13 (Fed. Cir. 2011). "Accordingly, inducement requires evidence of culpable conduct, directed to encouraging another's infringement, not merely that the inducer had knowledge of the direct

infringer's activities." *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006).

In the context of § 271(f)(1), a plaintiff would need to prove that the accused domestic manufacturer actively induced the combination of such components. Supplying a component to a third party abroad, without more, is not inducement under § 271(f)(1). In such a case, the domestic manufacturer would be the inducee, not the inducer, and no liability would attach.

The petitioners suggest that the domestic manufacturer would be liable if it were put on notice of the patent. Pet. Reply Br. 10. Putting aside whether a knowledge requirement even exists under § 271(f)(1)[2], it is certainly true that "[a] patentee may prove intent through circumstantial evidence," which can include knowledge of the patent. *Liquid Dynamics Corp.*, 449 F.3d at 1222 (quoting *Fuji Photo Film Co. v. Jazz Photo Corp.*, 394 F.3d 1368, 1377 (Fed. Cir. 2005)).

However, even if a domestic manufacturer was put on notice of a patent, for example by correspondence from the patent owner, and supplied a component that was combined abroad in a manner

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[2] "We need not reach the question whether the district court applied the correct standard under § 271(f)(1)," namely that the defendant knew the intended combination would be infringing if done domestically, because "[t]he verdict was clear that the jury found liability under § 271(f)(2) for all asserted claims." *WesternGeco L.L.C. v. ION Geophysical Corp.*, 791 F.3d 1340, 1348 (Fed. Cir. 2015), *judgment vacated on other grounds*, 136 S. Ct. 2486 (2016).

that would infringe the patent if combined in the U.S., this would still be insufficient to raise to the level of intent necessary to prove infringement under § 271(f)(1). *See id.* The accused manufacturer would have had to induce the combination abroad for liability to attach.

If the domestic manufacturer went further, for example, by providing instructions with the component identifying the other components needed and how to combine them, then the domestic manufacturer would come closer to having the requisite intent and may be liable under § 271(f)(1). Even under these circumstances, further information would be needed to determine whether liability would attach based on the specific facts—including, whether the component at issue was a "substantial portion of the components" of the invention.

In the instant case, the domestic manufacturer and the foreign party combining the components were deemed to be the same. And it is undisputed that LifeTech had both knowledge of the patent and the requisite intent to combine the supplied component with other components in a manner that would infringe the asserted patent if combined in the U.S. Pet. App. 34a. In most cases, however, inducement would not be "presumed," and would serve as an important limitation on the scope of § 271(f)(1).

3. The requirement that the supplied component be a "substantial portion" protects against § 271(f)(1) having overbroad scope.

The second safeguard on the scope of § 271(f)(1) is that a patent owner must prove that the component or components supplied abroad constitute a "substantial portion of a patented invention." 35 U.S.C. § 271(f)(1). In some cases, a single component may not be enough, but in this case, it is. The Wisconsin jury concluded that there was liability under § 271(f)(1), and the Federal Circuit held that there was sufficient record evidence to support a finding that *Taq* polymerase is a "substantial portion" of the invention. *See* Pet. App. 28a. These findings were appropriate.

Taq polymerase is profoundly important, both in the context of this case and in the field in general. *Taq* polymerase is the key ingredient in the polymerase chain reaction (PCR) method used to amplify DNA segments for further use and study. PCR is widely used in molecular biology. Indeed, *Taq* polymerase made possible many important discoveries and technological advancements including, sequencing the human genome, life saving vaccines and sophisticated forensic science. The 1993 Nobel Prize in Chemistry was awarded to Kary B. Mullis and Michael Smith for the invention of the PCR method. *The Nobel Prize in Chemistry 1993*, http://www.nobelprize.org/nobel_prizes/chemistry/laureates/1993/ (last visited Oct. 25, 2016). In 1989, Science Magazine named *Taq* polymerase its first "Molecule of the Year." Daniel E. Koshland, Jr., *The Molecule of the Year*, 246 Science 1541 (1989). And,

in 2013, the U.S. government gave the Golden Goose award to Thomas Brock and Hudson Freeze who discovered the *Thermus aquaticus* bacteria from which *Taq* polymerase originates. The Golden Goose Award, 2013: Thermus Aquaticus, http://www.goldengooseaward.org/awardees/c7vafs3ntt7jzovlxo68997rq5rxok (last visited Oct. 25, 2016).

The Court should affirm the Federal Circuit's conclusion that *Taq* polymerase was a substantial portion of the invention in the Tautz patent. There is no reason why a single component cannot be an important or essential part of a whole, as it is in other contexts. This is particularly true for a molecule as significant as *Taq* polymerase.

C. Numerous recent changes in patent law have provided additional protection against patents and claims of dubious merit.

An independent reason that the Court should not disturb the Federal Circuit's ruling is that recent changes to patent law have adjusted existing safeguards in the U.S. patent system. The patent system contains numerous delicate balances. While adjustments are necessary in a dynamic society, they should be made with care. It is too soon to know how these recent changes have affected the complex equilibrium of patent law.

For example, in 2006, this Court held that the traditional four-factor test that governs the award of permanent injunctive relief must be equally applied in patent cases. *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006). No longer are patent owners awarded injunctions based solely on a finding of infringement; injunctions are harder to obtain.

Post grant review procedures became available in 2012 with the enactment of the America Invents Act. Pub. L. No. 112-29, 125 Stat. 284 (2011). Parties defending against patents of dubious merit now have more expedient and cost effective alternatives to litigation to dispose of such threats.

That same year, in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. __, 132 S. Ct. 1289 (2012), this Court set a two part test for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts. Two years later, this Court provided further guidance to that two part test in *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. __, 134 S. Ct. 2347 (2014). The United States Patent and Trademark Office and courts now are better equipped to dispose of over-broad patents covering abstract ideas.

Accused infringers are well equipped to protect themselves from claims and patents of dubious merit. But all of these changes have affected the delicate balance between encouraging innovation and stifling competition. *See Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989). It is too soon to tell whether the scales are balanced or have been overcorrected. There is nothing presented in LifeTech's arguments or the facts of this case that warrant further adjustment of this balance.

IV. CONCLUSION

WARF respectfully submits that the Federal Circuit's decision should remain undisturbed. 35

U.S.C. § 271(f)(1) already includes adequate safeguards and no alteration in the law construing the provision is necessary at this time of significant change in American patent law.

Respectfully submitted,

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